



NDA 20-753/S-003

Pfizer Incorporated
Regulatory Affairs
235 East 42nd Street 150/7/5
New York, NY 10017

Attention: Melinda Rudnicki
Director, Worldwide Regulatory Strategy

Dear Ms. Rudnicki:

Please refer to your supplemental new drug application dated October 3, 2002, received October 7, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aromasin® (exemestane tablets).

We acknowledge receipt of your submissions dated February 24, June 4, October 7 and 9, 2003 on February 25, June 4, October 8 and 10, 2003.

This supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY, PRECAUTIONS, and DOSAGE AND ADMINISTRATION** sections of the package insert in order to address the concomitant use of exemestane with CYP 3A4 inducing agents.

We completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text. In addition, we acknowledge the final printed labeling (FPL) submitted on November 11, 1999, for the initial approval of NDA 20-753. This FPL will be retained with your files.

The final printed labeling (FPL) for S-003 must be identical to the enclosed labeling (text for the package insert).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-753/S-003." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Brenda Atkins, Regulatory Project Manager, at (301) 594-5767.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Richard Pazdur
11/13/03 09:44:28 AM